



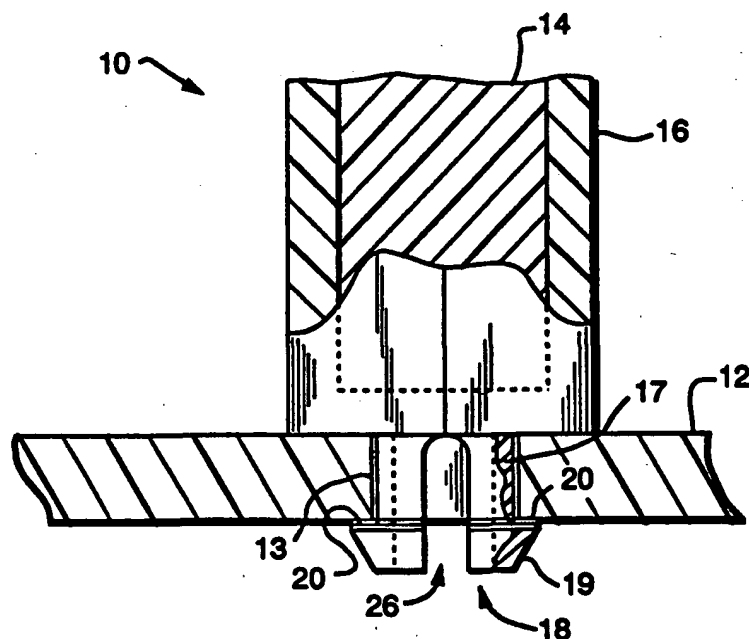
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<p>(21) International Application Number: PCT/US96/06595</p> <p>(22) International Filing Date: 9 May 1996 (09.05.96)</p> <p>(30) Priority Data: 08/438,604 10 May 1995 (10.05.95) US</p> <p>(71) Applicant: POLY VAC, INC. [US/US]; 1015 Candia Road, Manchester, NH 03109 (US).</p> <p>(72) Inventors: LATULIPPE, Michael, L.; 91 Old Auburn Road, Derry, NH 03038 (US). LEPAGE, Albert, A., Jr.; 110 Dean Street, Norton, MA 02871 (US).</p> <p>(74) Agent: SOLOWAY, Norman, P.; Hayes, Soloway, Hennessey, Grossman & Hage, 175 Canal Street, Manchester, NH 03101 (US).</p>		<p>(81) Designated States: European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report. With amended claims.</p>

(54) Title: STERILIZATION SUPPORT AND STORAGE CONTAINER SYSTEM

(57) Abstract

A support (14, 16) for medical instruments is provided to securely grasp the instrument during sterilization and storage. The support (14, 16) can be readily rearranged on a sterilization tray (12) and can be securely locked in whatever position is desired. It employs a novel arrangement of locking bayonet fingers (17) and a simple removal tool (22) for changing location of the support.



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STERILIZATION SUPPORT AND STORAGE CONTAINER SYSTEM

In the sterilization of surgical instruments it is desirable to have a sterilization tray assembly which will support the instruments during sterilization and can also be used for transporting and storing the instruments after sterilization. As instruments become larger and more complex, such as those used in endoscopy and orthoscopic procedures, it is necessary to provide a support having resilient contact with the surgical instrument and which can be securely positioned within the tray so that it will not be displaced during handling of the tray. Due to the appreciable weight and size of the surgical instruments this support may be subjected to considerable stress.

Since surgical instruments come in a wide variety of shapes and forms, and since it is impractical to have a single tray devoted to a particular type of surgical instrument, the art has developed numerous systems wherein supports for the surgical instruments can be provided in modular form and the various modules can be selectively positioned within the tray, for example, by plugging portions of the support elements through holes in a portion of the tray. The support elements can thus be arranged to match the shape of the surgical instrument to be sterilized.

Examples of such products are shown in U.S. Patent No. 4,135,868 to Sheinholz and U.S. Patent 5,384,103 to Miller. Similar products are commercially available from companies such as Poly-Vac, Incorporated, of Manchester, New Hampshire, and other suppliers. Some of these prior devices include integrally molded stubs, for example positioned on the bottom of the flexible inserts, which stubs can be locked into the vent bores in the tray as shown, for example, in Fig. 1 of Miller 5,384,103. They may also comprise separate, more rigid, holding elements such as shown in Fig. 3 of the above '103 patent where a rigid holder for the support element is be fastened by screws to the tray or an additional shelf carried by the tray. In the '868 patent, the support element for a soft sponge rubber, constituting a hold down pad, is supported by a channel member having outwardly extending buttons which can be forced into vent holes in the cover or base of the sterilizing tray. Another prior U.S. patent of interest, No. 4,798,292 shows hollow pegs having elongated legs which can be used for attachment to a perforated sterilizer tray.

While all of the systems described in the prior patents and commercially available products provide a certain amount of flexibility, they do not provide both strong security for the support members and low cost. Nor do they allow for ease of removal of a securely mounted support so that the supports can be differently positioned in the sterilization trays for holding different shapes of surgical instruments to be sterilized.

It is thus an object of the present invention to overcome the aforesaid and other disadvantages of the prior art. In the present invention the elements for claspings the surgical instruments are formed of resilient deformable members, as is well known in the art. These deformable members are secured within relatively rigid, strong, plastic support elements. These relatively rigid support elements have integrally formed fastening means which extend downwardly from the bottom surface of the support elements and have a size and shape designed to penetrate selected vent holes in the cover, base or support structure forming a part of the sterilization tray system. These fastening means lock the relatively rigid support element in a desired location. In addition, the fastening means are designed so that they can be readily removed by a simple tool which engages the ends of the fastening means and pushes them back through the holes in which they were previously securely locked in position.

Yet other objects and advantages of the present invention will be apparent from the following detailed description of the invention, taken in conjunction with the accompanying drawings wherein like numbers depict like parts, and wherein:

Fig. 1 is a schematic, partially sectional diagrammatic view of a portion of the sterilization tray which can be either the bottom, or top or insert tray, in a sterilization tray system of the type well known in the prior art;

Fig. 2 is an enlarged, schematic, partially sectional view of the fastening means and their relationship to the vent hole in the tray;

Fig. 3 is a schematic, partially sectional view of Fig. 2 showing the relationship of the fastening means and their heads with the tray removed and the fastening means in normal position;

Figs. 4A, 4B and 4C are respectively top, side and cross-sectional views of a half section of the support element 16 showing the fingers 17 and heads 18; and

Fig. 5 is a schematic partially sectional view showing the relationship of a removal tool forming a part of this invention and one of the heads of the fastening means.

Referring now to Figs. 1, 2 and 3 the sterilization tray element generally indicated at 10 may be any of the components of a sterilization system well known in the prior art. It can be a cover, bottom or separate shelf in the tray. A portion of this element 12 has a number of vent holes 13 for passage of sterilization fluids, as is well known in the art. Resilient clamp members, of any type well known in the art and which can take many shapes, are illustrated schematically at 14 as being carried by a support 16. From the bottom of the support 16 are downwardly extending elongated fingers 17 which terminate in enlarged heads 18.

Each enlarged head 18 has a conical end 19 and flat shoulder 20. As can be seen in the right hand side of Fig. 2, (which is partial sectional view along the line AA of Fig. 3,) the finger 17 is relatively thin and terminates in the shoulder 20. This shoulder is the back side of the external head 18. As can be seen, the shoulder 20 extends outwardly from the exterior portion of the finger 17. The fingers 17 are arcuate sections separated by spaces 26, thus providing necessary resilience to the fingers 17. When this set of fingers 17 is pushed down through the hole 13, each finger is moved radially by the conical surface 19 towards the axis of the hole so that each head 18 passes through the hole 13. The resilience of the finger 17 snaps the head outwardly and the shoulder 20 engages the backside of tray element 12. The arrangement of the fingers 17 and their enlarged heads 18 and shoulders 20 firmly secures the support 16 with respect to the tray 12 so that it is essentially impossible to accidentally remove support 16 from the tray, despite rough handling, dropping, etc.

In a preferred form of the invention the clamping member 14 is made of a resilient sterilizable material such as a synthetic rubber, as is well known in the medical art. The support element 16 is preferably molded from high impact strength semi-rigid medical grade, polymeric material or the like. Preferably, the two sets of four fingers 17 are integrally molded into the support elements 16 as shown in Figs 4A, 4B and 4C and are small arcs of a cylinder having about the same external diameter as hole 13. Preferably clamping member 14 is molded to shape and then positioned between two halves of the support element 16 and the whole assembly is affixed together, e.g. by means of ultrasonic welding. Alternatively, the assembly may be affixed together by adhesive means or by mechanical fastening means.

When it is desired to remove the support 16 for repositioning, for example a removal tool 22 is pressed against the head 18 of the fingers 17. This removal tool is shown in position in Fig. 5. Tool 22 preferably has an opening 24 slightly smaller than the size of the hole 13 in which the elongated fingers are locked. As the tool is moved upwardly, as seen in Fig. 5 against the conical surface 19 the slight taper 23 at the top of opening 24 in the removal tool engages the conical surface 19 and moves the head 18 towards the axis of the hole. Since the opening 24 is slightly smaller than the hole 13 it will compress the ends of the elongated fingers towards each other so that they have a compressed size smaller than hole 13. When the tool 22 finally is seated against the bottom of tray 12, the shoulders 20 will be moved out of engagement with the bottom surface of tray element 10 and the support element 16 can be easily detached from the tray.

While one preferred arrangement of fastening means is illustrated above, numerous modification thereof can be made without departing from the spirit of the invention. For example the fingers 17 can be planar rather than arcuate and the heads 18 can be triangular rather than conical. This latter arrangement would be preferable where the hole 13 is rectangular rather than circular. In this case the opening 24 in the tool 22 would be a slot slightly narrower than hole 13.

We claim:

1. In a sterilization tray assembly for sterilizing surgical instruments, said assembly including a structure 12 having a plurality of holes 13 and a resiliently deformable member for clasp ing surgical instruments; the improvement comprising a relatively rigid plastic support element 16 connected to said deformable member 14 and being for predeterminedly positioning said resiliently deformable member with respect to different holes 13 in said structure, wherein said relatively rigid support element has integrally formed fastening means 17 downwardly extending from a bottom surface of said support element and positioned to penetrate predetermined holes of said structure to lock said support element in position, said fastening means having heads 18 which extend through said predetermined holes when said fastening means penetrate said predetermined holes, each said head being adapted to be engaged by an opening of a removal tool 22 for deforming said heads when said heads extend through said predetermined holes to thereby release said fastening means from said predetermined holes, each said head comprising a plurality of outwardly extending shoulders 20 for engaging said structure when said heads extend through predetermined holes, said shoulders being separated by spaces 26 for permitting said heads to collapse to a size smaller than said predetermined holes when said tool engages said heads whereby to disengage said shoulders from said structure.

2. The assembly of claim 1, wherein said heads 18 each comprise a conical surface 19 for being engaged by said tool 22 and a shoulder 20 for engaging said structure when said heads extend through said predetermined holes whereby to lock said support element in position.

3. The assembly of claim 1 wherein said fastening means comprises at least two fingers 17.

4. The assembly of claim 1 wherein said fastening means have tapered ends 19.

5. The assembly of claim 1, wherein each said head 18 comprises a plurality of shoulders 20.

6. In a combination including a sterilization tray assembly for sterilizing surgical instruments, said assembly including a structure 12 having a plurality of holes 13 and a resiliently deformable member 14 for clasp ing surgical instruments; the improvement

comprising a relatively rigid plastic support element 16 connected to said deformable member and being for predeterminedly positioning said resiliently deformable member with respect to different holes in said structure, and said relatively rigid support element 16 has integrally formed fastening means including fingers 17 having respective tapered heads 18 and downwardly extending from a bottom surface of said support element and positioned to penetrate predetermined holes 13 of said structure to lock said support element in position, said combination also including a removal tool 22 for releasing said fingers 17 from predetermined holes 13 into which said fingers have penetrated, said tool including an opening 24 adapted and operatively positioned to engage the tapered head 18 on each said finger 17 when said fingers penetrate said predetermined holes whereby to deform said fingers to release said fingers from said predetermined holes, said opening 24 being slightly smaller than said hole 13.

7. The assembly of claim 6 wherein said tapered ends 19 are conically shaped.

8. The combination of claim 6 wherein said fastening means comprises at least two fingers 17 having partial conical surfaces 19, and the holes 13 in the structure 12 and the opening 24 of the tool 22 are both circular.

9. The combination of claim 6, wherein said fingers 17 also include surfaces 20 for extending out of said predetermined holes 13 and engaging said structure 12 when said fingers penetrate said holes.

10. The combination of claim 6, wherein the heads 18 of said fingers 17 each comprise a conical surface 19 for being engaged by said tool 22 and a shoulder 20 for engaging said structure 12 when said fingers 17 penetrate said predetermined holes 13.

11. The combination of claim 6, wherein each said head 18 comprises a plurality of shoulders 20 for engaging said structure when said fingers 17 penetrate said predetermined holes 13, said shoulders 20 being separated by spaces 26 for permitting said heads to collapse to a size smaller than said predetermined holes 13 when said tool 22 engages said heads whereby to disengage said shoulders 20 from said structure 12.

AMENDED CLAIMS

[received by the International Bureau on 21 August 1996 (21.08.96);
original claims 1-11 replaced by amended claims 1-11 (3 pages)]

1

2 1. In a sterilization tray assembly for sterilizing surgical instruments, said
3 assembly including a structure (12) having a plurality of straight walled holes (13) and
4 a resiliently deformable member for clasp ing surgical instruments; the improvement
5 comprising a relatively rigid plastic support element (16) connected to said
6 deformable member (14) and being for predetermined ly positioning said resiliently
7 deformable member with respect to different holes (13) in said structure, wherein said
8 relatively rigid support element has integrally formed fastening means (17)
9 downwardly extending from a bottom surface of said support element and positioned
10 to penetrate predetermined holes of said structure to lock said support element in
11 position, said fastening means comprising a plurality of flexible fingers (17) having
12 sufficient length to extend through said holes, said fingers having enlarged heads (18)
13 which extend beyond said predetermined holes when said fastening means penetrate
14 said predetermined holes, each said head being constructed to be engaged by an
15 opening of a removal tool (22) for deforming said heads when said heads extend
16 through said predetermined holes to thereby release said fastening means from said
17 predetermined holes, each said head comprising a plurality of outwardly extending
18 shoulders (20) for engaging said structure whereby to lock said support element in
19 position when said heads extend through predetermined holes, said shoulders being
20 separated by spaces (26) for permitting said heads to collapse to a size smaller than
21 said predetermined holes when said tool engages said heads whereby to disengage
22 said shoulders from said structure.

23 2. The assembly of claim 1, wherein said heads (18) each comprise a conical
24 surface (19) for being engaged by said tool (22) and a shoulder (20) for engaging said
25 structure when said heads extend through said predetermined holes whereby to lock
26 said support element in position.

27 3. The assembly of claim 1 wherein said fastening means comprises at least
28 two fingers (17).

29 4. The assembly of claim 1 wherein said fastening means have tapered ends
30 (19).

1 5. The assembly of claim 1, wherein each said head (18) comprises a plurality
2 of shoulders (20).

3 6. In a combination including a sterilization tray assembly for sterilizing
4 surgical instruments, said assembly including a structure (12) having a plurality of
5 holes (13) and a resiliently deformable member (14) for clasp ing surgical instruments;
6 the improvement comprising a relatively rigid plastic support element (16) connected
7 to said deformable member and being for predeterminedly positioning said resiliently
8 deformable member with respect to different holes in said structure, and said
9 relatively rigid support element (16) has integrally formed fastening means including
10 fingers (17) having respective tapered heads (18) and downwardly extending from a
11 bottom surface of said support element and positioned to penetrate predetermined
12 holes (13) of said structure to lock said support element in position, said combination
13 also including a removal tool (22) for releasing said fingers (17) from predetermined
14 holes (13) into which said fingers have penetrated, said tool including an opening (24)
15 adapted and operatively positioned to engage the tapered head (18) on each said
16 finger (17) when said fingers penetrate said predetermined holes whereby to deform
17 said fingers to release said fingers from said predetermined holes, said opening (24)
18 being slightly smaller than said hole (13).

19 7. The assembly of claim 6 wherein said heads each comprise a conical
20 surface (19) for being engaged by said tool.

21 8. The combination of claim 6 wherein said fastening means comprises at
22 least two fingers (17) having partial conical surfaces (19), and the holes (13) in the
23 structure (12) and the opening (24) of the tool (22) are both circular.

24 9. The combination of claim 6, wherein said fingers (17) also include surfaces
25 (20) for extending out of said predetermined holes (13) and engaging said structure
26 (12) when said fingers penetrate said holes.

27 10. The combination of claim 6, wherein the heads (18) of said fingers (17)
28 each comprise a conical surface (19) for being engaged by said tool (22) and a
29 shoulder (20) for engaging said structure (12) when said fingers (17) penetrate said
30 predetermined holes (13).

1 11. The combination of claim 6, wherein each said head (18) comprises a
2 plurality of shoulders (20) for engaging said structure when said fingers (17) penetrate
3 said predetermined holes (13), said shoulders (20) being separated by spaces (26) for
4 permitting said heads to collapse to a size smaller than said predetermined holes (13)
5 when said tool (22) engages said heads whereby to disengage said shoulders (20) from
6 said structure (12).

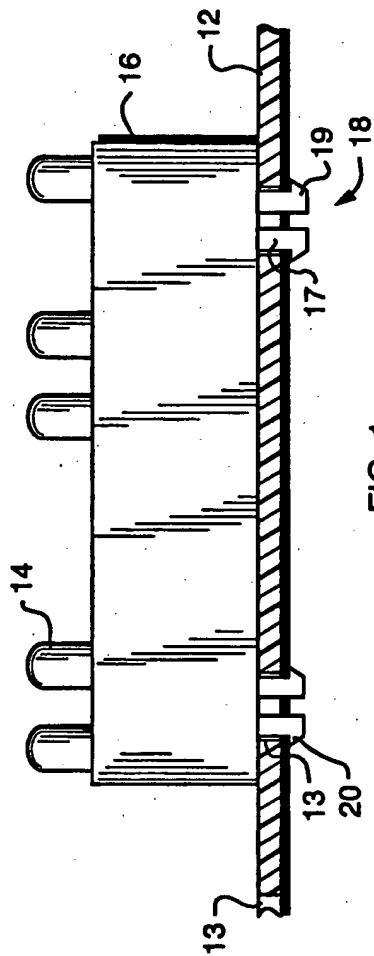


FIG. 1

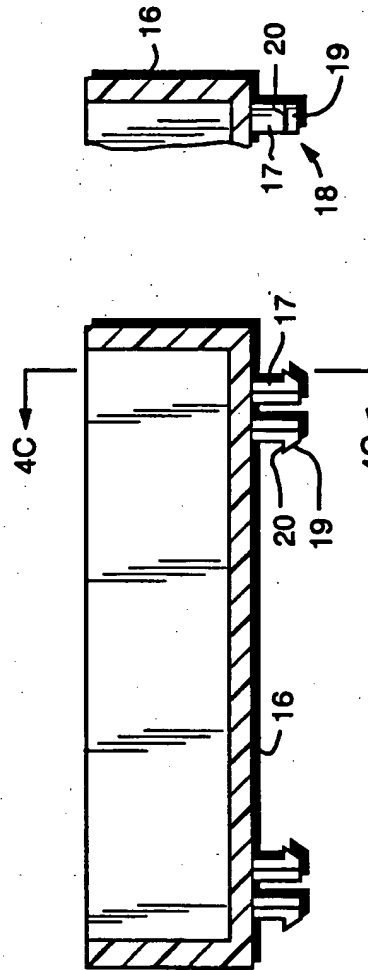


FIG. 4B

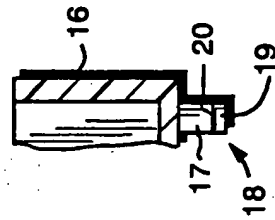


FIG. 4C



FIG. 4A

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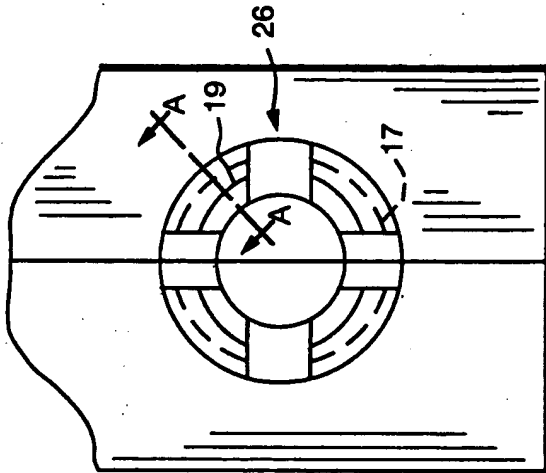


FIG. 3

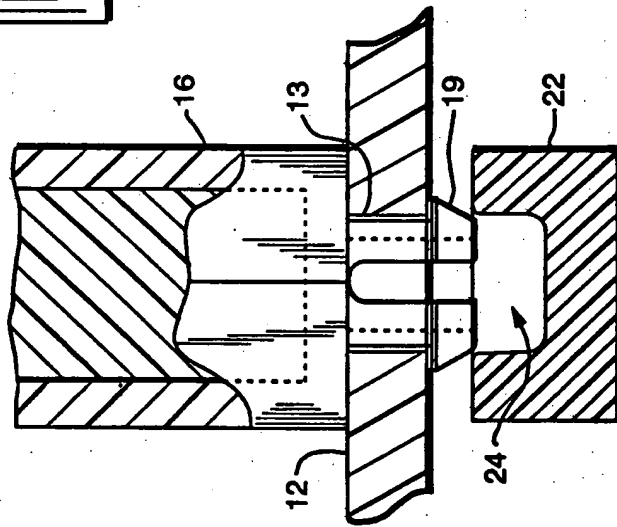


FIG. 5

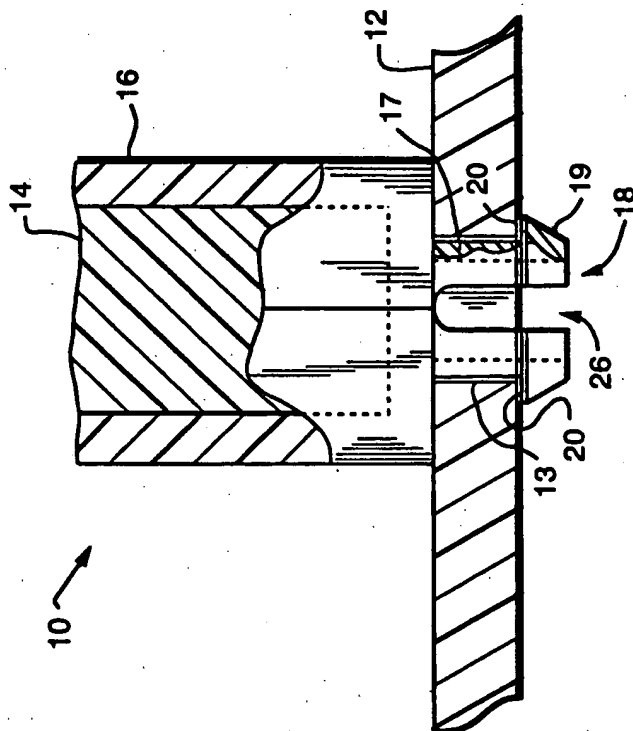


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/06595

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61L 2/26; B65D 1/36; F16B 19/02, 21/04

US CL :422/297, 300, 310; 206/438, 439, 560; 24/704.1; 411/509, 913

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/297, 300, 310; 206/63.5, 438, 439, 487, 560, 562, 563; 24/289, 297, 453, 704.1; 411/508, 509, 913

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,135,868 (SCHAINHOLZ) 23 Jan 1979, col. 2, lines 38, 51-53, 64-65, col. 3, lines 17-32, fig. 3, #36-39,50.	1
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Y		2-5
Y	US, A, 5,143,500 (SCHURING ET AL.) 01 Sept 1992, fig. 1, #42,42,48-49, fig. 8, #140, col. 2, lines 54-59, col. 3, line 34.	2-5
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A		6-11
A	US, A, 5,384,103 (MILLER) 24 Jan 1995, see entire document.	1-11
A	US, A, 4,798,292 (HAUZE) 17 Jan 1989, see entire document.	1-11
A	US, A, 4,953,269 (RAGSDALE) 04 Sept 1990, see entire document.	1-11

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

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PCT/US96/06595

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,184,377 (RAGSDALE ET AL.) 09 Feb 1993, see entire document.	1-11
A	US, A, 3,908,235 (TELLIARD ET AL.) 30 Sept 1975, see entire document.	1-11